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December 7, 2004

VIA OVERNIGHT MAIL

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1051
Rockville, Maryland 20852

RE: In re: Korangy Radiology Associates, P.A., *et al.*
FDA Docket No. 2003H-0432

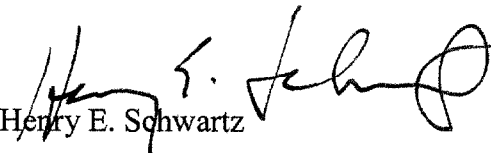
Dear Sir/Madam:

Enclosed for filing in the above-referenced matter please find an original and one copy of the Respondents' Motion to Strike.

A draft order is also enclosed.

Thank you for your attention to this filing. Please contact me with any questions.

Sincerely,


Henry E. Schwartz

Enclosures

cc: Amile Korangy, M.D.
Jennifer E. Dayok, Esquire
Marci Norton, Esquire
Hon. Daniel J. Davidson, ALJ

2003H-0432

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of

*

KORANGY RADIOLOGY ASSOCIATES, P.A.,
Trading as BALTIMORE IMAGING CENTERS,
A corporation,

ADMINISTRATIVE
COMPLAINT FOR
CIVIL MONEY PENALTY

*

And

FDA Docket: 2003H-0432

AMILE A. KORANGY, M.D.,
An individual

*

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RESPONDENTS' MOTION TO STRIKE

Now come Respondents, Korangy Radiology Associates, P.A., t/a Baltimore Imaging Centers ("BIC") and Amile A. Korangy, M.D. ("Dr. Korangy"), by their attorneys, Henry E. Schwartz, and Henry E. Schwartz LLC, and file the following Motion to Strike. All references herein are intended to apply to both Respondents, unless specified to the contrary.

1. Complainants, with their Post-Hearing Brief, have included as Docket item G-31, an alleged FDA policy document. This document is presented, and relied upon, in rebuttal to testimony provided by Complainant's own witness, Mr. Devine. He testified that FDA had no guidelines or standards indicating "when and how" CMPs were to be applied. Item G-31 was not presented by FDA prior to the hearing, as required, nor was it presented at the hearing, where Respondents might have had an opportunity to review the document, and cross-examine the FDA's expert witness concerning the document.

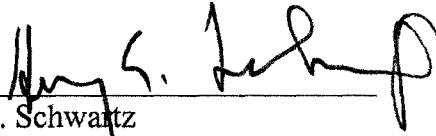
Accordingly, the provision of Docket item G-31 in the Post-Hearing Brief is inappropriate and prejudicial.

2. Complainants, with their Post-Hearing Brief, have included as Docket items G-15-25, and 27-29, various documents allegedly demonstrating assets that in some fashion are allegedly under the past or current control of Respondent Korangy. These documents were not presented pre-hearing, or during the hearing, so Respondents' have no opportunity to respond or cross-examine any witnesses regarding the allegations made with respect to these documents.

Accordingly, the provision of Docket items G-15-25 and 25-29 are inappropriate and prejudicial.

For the foregoing reasons, Respondents hereby move for the striking of Docket items G-15 through G-25, G-27 through G-29, and G-31, and all references to such documents, from the record in the instant case.

Respectfully submitted on behalf of Respondents, by:

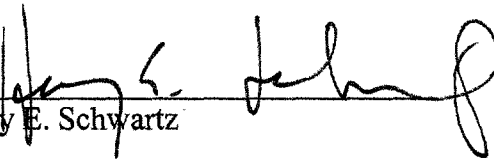


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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 7th day of December, 2004, a copy of the foregoing Respondents' Motion to Strike was mailed, first class, postage prepaid, to Complainant's Counsel, as follows:

Marci Norton, Esquire
Jennifer Dayok, Esquire
The Center for Devices and Radiological Health
United State Food and Drug Administration
5600 Fishers Lane (GCF-1)
Rockville, MD 20857


Henry E. Schwartz

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of

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KORANGY RADIOLOGY ASSOCIATES, P.A.,
Trading as BALTIMORE IMAGING CENTERS,
A corporation,

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ADMINISTRATIVE
COMPLAINT FOR
CIVIL MONEY PENALTY

And

FDA Docket: 2003H-0432

AMILE A. KORANGY, M.D.,
An individual

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* * * * *

PROPOSED ORDER

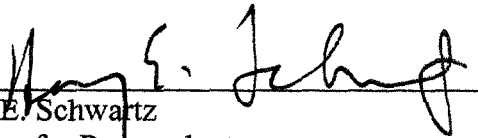
Respondents filed a request for the striking of Docket items G-15 through G-25, G-27 through G-29, and G-31, on the basis that they were not presented prior to, or at, the hearing in this matter, and were therefore inappropriate and prejudicial.

Accordingly, it is ORDERED, ADJUDGED, AND DECREED, that:

Respondents' request for the striking of Docket items G-15 through G-25, G-27 through G-29, and G-31, is GRANTED.

Daniel J. Davidson
Administrative Law Judge
U.S. Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, MD 20857

Proposed by:

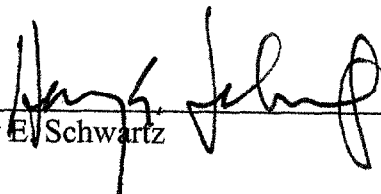


Henry E. Schwartz
Attorney for Respondents

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 7th day of December, 2004, a copy of the foregoing Proposed Order was mailed, first class, postage prepaid, to Complainant's Counsel, as follows:

Jennifer Dayok, Esquire
The Center for Devices and Radiological Health
United State Food and Drug Administration
5600 Fishers Lane (GCF-1)
Rockville, MD 20857
Telephone: 301.827.1141



Henry E. Schwartz